We claim:

1. A sustained release tablet comprising:
gabapentin or a pharmaceutically acceptable salt or hydrate thereof; and
at least one rate- controlling polymer;
wherein the tablet provides therapeutically effective plasma levels of gabapentin for a period of up to about 12 hours.

2. The sustained release tablet of claim 1, wherein the tablet exhibits the following in-vitro dissolution profile when measured in a USP type II dissolution apparatus at 50 rpm, a temperature of 37°C ±0.5°C in 900 ml of 0.06 N hydrochloric acid:
at most approximately 50% of the drug is released in 1 hour,
at most approximately 65% of the drug is released in 2 hours, and
at most approximately 85% of the drug is released in 4 hours.

3. The sustained release tablet of claim 1, wherein administering the tablet twice per day provides comparable bioavailability with respect to a tablet or capsule containing gabapentin administered three times per day under fasting conditions for similar cumulative daily dose.

4. The sustained release tablet of claim 1, wherein the gabapentin comprises from about 100 mg to about 1200 mg by weight of the tablet.

5. The sustained release tablet of claim 1, wherein the rate-controlling polymer comprises from about 5% to about 80% by weight of the tablet.

6. The sustained release tablet of claim 5, wherein the rate-controlling polymer comprises from about 5% to about 70% by weight of the tablet.

7. The sustained release tablet of claim 6, wherein the rate-controlling polymer comprises from about 5% to about 60% by weight of the tablet.

8. The sustained release tablet of claim 1, wherein the rate-controlling polymer comprises one or more of polyvinylpyrrolidone, cellulosic polymer, vinylacetate copolymers,

alginate, xanthan gum, guar gum, starch and starch based polymers, polyethylene oxide, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives, ethyl cellulose, cellulose acetate, methacrylates, acrylic acid polymers and copolymers, high molecular weight polyvinyl alcohols, and waxes.

9. The sustained release tablet of claim 8, wherein the rate-controlling polymer comprises a cellulosic polymer.

10. The sustained release tablet of claim 9, wherein the cellulosic polymer comprises one or more of hydroxypropyl methylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, and methylcellulose.

11. The sustained release tablet of claim 10, wherein the cellulosic polymer comprises hydroxypropyl methylcellulose.

12. The sustained release tablet of claim 11, wherein the hydroxypropyl methylcellulose has a viscosity of about 100 cps to about 100,000 cps.

13. The sustained release tablet of claim 12, wherein the hydroxypropyl methylcellulose has a viscosity of about 4,000 cps to about 15,000 cps.

14. The sustained release tablet of claim 10, wherein the cellulosic polymer comprises hydroxypropylcellulose.

15. The sustained release tablet of claim 14, wherein the hydroxypropylcellulose has a viscosity of about 7 cps to about 30,000 cps.

16. The sustained release tablet of claim 15, wherein the hydroxypropylcellulose has a viscosity of about 4000 cps to about 15,000 cps.

17. The sustained release tablet of claim 10, wherein the cellulosic polymer comprises hydroxyethylcellulose.

18. The sustained release tablet of claim 1, further comprising one or more excipients, wherein the excipients comprise one or more of diluents, lubricants, glidants, binders, and stabilizers.

19. The sustained release tablet of claim 18, wherein the diluent comprises one or more of powdered sugar, calcium phosphate, calcium sulfate, microcrystalline cellulose, lactose, mannitol, kaolin, dry starch, and sorbitol.

20. The sustained release tablet of claim 18, wherein the lubricant comprises one or more of talc, stearic acid, vegetable oil, calcium stearate, zinc stearate, and magnesium stearate.

21. The sustained release tablet of claim 18, wherein the glidant comprises one or more of talc, silicon dioxide, and cornstarch.

22. The sustained release tablet of claim 18, wherein the binder comprises one or more of polyvinylpyrrolidone, polyvinylpyrrolidone/vinylacetate copolymer, xanthan gum, guar gum, cellulose gums, carboxymethylcellulose, methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, gelatin, starch, and pregelatinized starch.

23. The sustained release tablet of claim 18, wherein the stabilizer comprises poloxamer.

24. The sustained release tablet of claim 1, wherein the tablet is configured to release the gabapentin in the stomach.

25. The sustained release tablet of claim 1, wherein the tablet releases the gabapentin by a combination of diffusion and erosion.

26. The sustained release tablet of claim 1, wherein the rate controlling polymer swells to form a polymeric matrix after contact with fluid having properties of gastric fluids.

27. A process for the preparation of a sustained release tablet of gabapentin, the process comprising:
granulating a mixture comprising gabapentin or a pharmaceutically acceptable salt or hydrate thereof and at least one rate-controlling polymer with one or both of water and a binder solution; and

compressing the granules into a tablet,

wherein the tablet provides therapeutically effective plasma levels of gabapentin for a period of up to about 12 hours.

28. The process of claim 27, wherein the tablet exhibits the following in-vitro dissolution profile when measured in a USP type II dissolution apparatus, at 50 rpm, a temperature of 37°C ± 0.5°C in 900 ml of 0.06 N hydrochloric acid:

at most about 50% of the drug is released in 1 hour,

at most about 65% of the drug is released in 2 hours, and

at most about 85% of the drug is released in 4 hours.

29. The process of claim 27, wherein administering the tablet twice per day provides comparable bioavailability with respect to a tablet or capsule containing gabapentin administered three times per day under fasting conditions for similar cumulative daily dose.

30. The process of claim 27, wherein the rate-controlling polymer comprises from about 5% to about 80% by weight of the tablet.

31. The process of claim 27, wherein the rate-controlling polymer comprises from about 5% to about 60% by weight of the tablet.

32. The process of claim 27, wherein the rate-controlling polymer comprises one or more of polyvinylpyrrolidone, cellulosic polymer, vinylacetate copolymers, alginate, xanthan gum, guar gum, starch and starch based polymers, polyethylene oxide, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives, ethyl cellulose, cellulose acetate, methacrylates, acrylic acid polymers and copolymers, high molecular weight polyvinyl alcohols, and waxes.

33. The process of claim 32, wherein the rate-controlling polymer comprises a cellulosic polymer.

34. The process of claim 33, wherein the cellulosic polymer comprises one or more of hydroxypropyl methylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, and methylcellulose.

35. The process of claim 34, wherein the cellulosic polymer comprises hydroxypropyl methylcellulose having a viscosity of about 100 cps to about 100,000 cps.

36. The process of claim 34, wherein hydroxypropyl methylcellulose has a viscosity of about 4,000 cps to about 15,000 cps.

37. The process of claim 34, wherein the cellulosic polymer comprises hydroxypropylcellulose having a viscosity of about 7 cps to about 30,000 cps.

38. The process of claim 37, wherein the hydroxypropylcellulose has a viscosity of about 4,000 cps to about 15,000 cps.

39. The process of claim 34, wherein the cellulosic polymer comprises hydroxyethylcellulose.

40. The process of claim 27, wherein the mixture further comprises one or more of diluent, lubricant, glidant, binder, and stabilizer.

41. The process of claim 40, wherein the diluent comprises one or more of powdered sugar, calcium phosphate, calcium sulfate, microcrystalline cellulose, lactose, mannitol, kaolin, dry starch, and sorbitol.

42. The process of claim 40, wherein the lubricant comprises one or more of talc, stearic acid, vegetable oil, calcium stearate, zinc stearate, and magnesium stearate.

43. The process of claim 40, wherein the glidant comprises one or more of talc, silicon dioxide, and cornstarch.

44. The process of claim 40, wherein the binder comprises one or more of polyvinylpyrrolidone, polyvinylpyrrolidone/vinylacetate copolymer, xanthan gum, guar gum, cellulose gum, carboxymethylcellulose, methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, gelatin, starch, and pregelatinized starch.

45. The process of claim 40, wherein the stabilizer comprises poloxamer.

46. The sustained release tablet of claim 27, wherein the rate controlling polymer swells to form a polymeric matrix after contact with fluid having properties of gastric fluids.

47. A process for the preparation of a sustained release tablet of gabapentin, the process comprising:

forming granules by granulating a mixture of a therapeutically effective amount of gabapentin or a pharmaceutically acceptable salt or hydrate thereof, about 5% to about 80% by weight of the tablet of hydroxypropyl methylcellulose having a viscosity of about 100 cps to about 100,000 cps, and one or more pharmaceutical excipients with water or a binder solution; and

compressing the granules into a tablet,

wherein the tablet provides therapeutically effective plasma levels of gabapentin for a period of up to about 12 hours upon administration to a mammal.

48. A process for the preparation of sustained release tablet of gabapentin, the process comprising:

granulating a mixture of a therapeutically effective amount of gabapentin or a pharmaceutically acceptable salt or hydrate thereof, about 5% to about 80% by weight of the tablet of hydroxypropylcellulose having a viscosity of about 7 cps to about 30,000 cps, and one or more pharmaceutical excipients with water or a binder solution; and compressing the granules into a tablet;

wherein the tablet provides therapeutically effective plasma levels of gabapentin for a period of up to about 12 hours.

49. A method of treating a medical condition, the method comprising providing an oral, pharmaceutical sustained release dosage form comprising gabapentin and at least one rate controlling polymer,

wherein the sustained release dosage form provides therapeutically effective plasma levels of gabapentin for a period of up to about 12 hours..

50. The method of treatment according to claim 49, wherein the medical condition comprises epilepsy.

51. The method of treatment of claim 49, wherein the sustained release tablet is configured to release the gabapentin in the stomach.

52. The method of treatment of claim 49, wherein the sustained release tablet releases the gabapentin by a combination of diffusion and erosion.

53. The method of treatment of claim 49, wherein the rate controlling polymer swells to form a polymeric matrix after contact with gastric fluids.